

COMBINED TRANSMITTAL OF APPEAL BRIEF TO THE BOARD OF PATENT
APPEALS AND INTERFERENCES & PETITION FOR EXTENSION OF TIME
UNDER 37 C.F.R. 1.136(a) (Large Entity)

Docket No.
P02977

In Re Application Of: SUZANNE F. GROEMMINGER

Serial No.
09/737,004

Filing Date
DECEMBER 14, 2000

Examiner
G. R. DELCOTTO

Group Art Unit
1751

Invention: COMPOSITION FOR CLEANING AND WETTING CONTACT LENSES

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TO THE ASSISTANT COMMISSIONER FOR PATENTS:

This is a combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition under the provisions of 37 CFR 1.136(a) to extend the period for filing an Appeal Brief.

Applicant(s) hereby request(s) an extension of time of (check desired time period):

☐ One month ☐ Two months ☒ Three months ☐ Four months ☐ Five months

from: NOVEMBER 16, 2003 until: FEBRUARY 16, 2004
Date Date

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Fee for Appeal Brief: \$300.00

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- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
☒ Any patent application processing fees under 37 CFR 1.17.

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Docket No.
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FEB 02 2004

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In Re Application Of: SUZANNE F. GROEMMINGER

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Invention: COMPOSITION FOR CLEANING AND WETTING CONTACT LENSES

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

This combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition for extension of time under 37 CFR 1.136(a) is respectfully submitted by the undersigned:


Signature

Reg. No. 33,624 Dated: JANUARY 29, 2004

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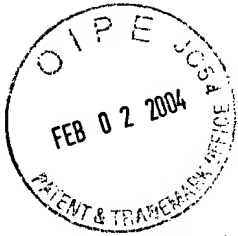


Signature of Person Mailing Correspondence

RITA D. VACCA

Typed or Printed Name of Person Mailing Correspondence

CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Suzanne F. Groemminger)
Serial No.: 09/737,004)
Filed: December 14, 2000)
Title: COMPOSITIONS FOR CLEANING AND)
WETTING CONTACT LENSES)

Examiner: G. Delcotto
Group No.: 1751
Docket No: P02977

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Director of the United States Patent and Trademark Office, Washington, D.C. 20231, on January 29, 2004.


Rita D. Vacca

APPEAL BRIEF
(37 C.F.R. 1.192)

Director of the United States Patent and Trademark Office
Washington, D.C. 20231
ATTENTION: Board of Patent Appeals and Interferences

Sir:

By Notice of Appeal filed on or after September 16, 2003, applicants appeal the Final Rejection in the above-identified application dated April 22, 2003, and submit this Brief (in triplicate) in support thereof. A Petition requesting a three (3) month extension of time under 37 C.F.R. 1.136 within which to file Appellant's brief under 37 C.F.R. 1.192 is enclosed herewith. Authorization to charge the fee under 37 C.F.R. 1.17(a)(3) and 1.17(c) to Deposit Account No. 02-1425 is provided in the transmittal letter accompanying this Appeal Brief.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Bausch & Lomb Incorporated, as evidenced by the Assignment recorded at Reel 012281/Frame 0021.

II. RELATED APPEALS AND INTERFERENCES

Applicants are not aware of any other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

Claims in the application are 1-20.

B. Status of All the Claims

Claims 13-20 are withdrawn from consideration.

Claims 1-12 are currently pending.

Claims 1-12 stand rejected.

C. Claims on Appeal

Claims 1-12 form the basis of this appeal.

IV. STATUS OF AMENDMENTS

The status of the amendment filed February 7, 2003 was entered and an explanation of how the new or amended claims would be rejected was provided in the Office Action of April 22, 2003 and confirmed in the Advisory Action of July 22, 2003.

V. SUMMARY OF INVENTION

Generally, the claimed invention relates to cleaning and wetting compositions that provide improved cleaning, i.e., improved removal of contact lens deposits, as well as less eye irritation as compared to the commercialized compositions of U.S. Patent Number 5,604,189. Also, the preferred embodiments of the subject compositions are effective at disinfecting a contact lens, yet employs a lower amount of antimicrobial agent, thus, further alleviating the potential for eye irritation.

As discussed at **p. 2, line 10** of the specification, the aqueous composition for cleaning and wetting a contact lens of the present invention comprises a non-amine polyethyleneoxy-containing material having an HLB value of at least about 18, **p. 2, line 12**; a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine, **p. 2, line 14**; a second non-ionic surface active agent having cleaning activity for contact lens deposits and that comprises a non-poloxamine surface active agent with an HLB value less than that of said non-amine polyethyleneoxy-containing material, **p. 2, line 16 and p. 4, line 17**; and a wetting agent, **p. 2, line 18**.

The non-amine polyethyleneoxy-containing material comprises about 0.001 to about 10 weight percent, **p. 4, line 2** or about 0.001 to about 5 weight percent, **p. 4, line 2** of the composition and is at least one member selected from the group consisting of poloxamers, ethoxylated glucose derivatives, ethoxylated nonionic ethers of sorbitol, and ethoxylated nonionic ethers of glycerol having an HLB value of at least about 18, **p. 2, line 30**.

The first non-ionic surface active agent comprises about 0.001 to about 5 weight percent, **p. 4, line 28** or about 0.001 to 2 weight percent, **p. 4, line 29** of the composition.

The second non-ionic surface active agent comprises about 0.001 to about 5 weight percent, **p. 4, line 28** of the composition and comprises at least one member selected from the group consisting of poloxamers having an HLB value less than 18, ethoxylated alkyl phenols, polysorbates, alkyl glucosides and polyglucosides, **p. 4, lines 17-25**.

The wetting agent comprises about 0.1 to about 10 weight percent, **p. 5, line 19** of the composition and is at least one member selected from the group consisting of cellulosic materials, polyvinyl alcohols, polyvinyl pyrrolidones and silicone polymers having a pendant alkyleneoxide side chain, **p. 5, lines 6-8**.

The composition could likewise include a buffering agent, **p. 5, line 20** or a tonicity agent, **p. 5, line 21**, and the eye irritation potential of the composition is sufficiently low that a lens wetted with the same can be inserted directly in the eye, **p. 7, line 1**.

Independent claim 1 defines an aqueous composition for cleaning and wetting a contact lens comprising a non-amine polyethyleneoxy-containing material having an HLB value of at least about 18; a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine; a second non-ionic surface active agent having cleaning activity for contact lens deposits and that comprises a non-poloxamine surface active agent with an HLB value less than that of said non-amine polyethyleneoxy-containing material; and a wetting agent.

The aqueous composition for cleaning and wetting a contact lens may be provided as formulations with weight percent ranges for the components and various components of the composition may be present in a particular form. These features are specifically claimed in dependent claims 2-9. Dependent claim 10 defines the composition of claim 1 with the addition of a buffering agent or tonicity agent. Dependent claim 11 further defines the composition of claim 1 such that the eye irritation potential of the composition is sufficiently low that a contact lens wetted with the same can be inserted directly into the eye. Dependent claim 12 further defines the composition of claim 1 with each component thereof in a particular form.

VI. ISSUES

The issues raised by this appeal are:

Whether claims 1-12 were improperly rejected as unpatentable under 35 U.S.C. 103(a) over Hu et al., (WO 00/37049); and

Whether claims 1-4 and 6-11 were improperly rejected as unpatentable under 35 U.S.C. 103(a) over Heiler et al., (WO 97/43373).

VII. GROUPING OF CLAIMS

Claims 1-9 stand or fall together.

Claims 10 and 12 stand or fall together.

Claim 11 stands or falls alone.

VIII. ARGUMENTS

Claims 1-12 were improperly rejected as unpatentable under 35 U.S.C. 103(a) over Hu et al., (WO 00/37049).

A. The Cited Reference

Hu et al., teach an ophthalmic solution for the treatment of contact lenses while worn in the eye **to prevent** lipid or protein deposition thereon. In particular, the ophthalmic solution contains an ethoxylated glucose derivative as a wetting agent employed in amounts from about 0.01 to about 5 weight percent but preferably 0.1 to 2 weight percent,

tyloxapol as a cleaning agent employed in amounts from about 0.01 to about 1.0 weight percent and a polyoxyethylene-polyoxypropylene nonionic surfactant as a comfort agent having an HLB of at least 18 employed in amounts from about 0.01 to about 10 weight percent but preferably 0.1 to 5 weight percent.

B. Claims 1-9

Applicants submit that no *prima facie* case of obviousness has been established. Hu et al. does not teach the present invention or the surprising beneficial effects thereof, such as effective contact lens cleaning of built-up or accumulated deposits of proteins and/or lipids thereon, while remaining gentle enough for direct placement in an eye. The subject compositions comprise a non-amine polyethyleneoxy-containing material having an HLB value of at least 18, a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine, a second non-ionic surface active agent having cleaning activity for contact lens deposits with an HLB value less than that of said non-amine polyethyleneoxy-containing material and a wetting agent, for improved **removal of** contact lens deposits. Hu et al., '049 does not teach **dual cleaning agents for improved removal of lens deposits**, in addition to comfort agents and wetting agents, as is claimed in the present invention. As known to those skilled in the art, compositions effective in **preventing** deposits on contact lenses (Hu et al.) are not necessarily effective in **removing** deposits from contact lenses, and thereby one is not made obvious in view of the other. Accordingly, the subject compositions with dual function cleaning agents differ significantly

from the teachings of Hu et al., for the prevention of lipid or protein lens depositions. For these reasons, a *prima facie* case of obviousness has not been established based on Hu et al. Withdrawal of the rejection of claims 1-12 under 35 U.S.C. 103(a) over Hu et al. is respectfully requested.

C. Claims 10 and 12

Dependent claims 10 and 12 define compositions of claim 1 with the addition of buffering agents and/or tonicity adjusting agents. For the same reasons stated in section VIII.B., *supra*, no *prima facie* case of obviousness has been established against these claims.

As the cited reference fails to teach the compositions of claims 10 and 12, the rejection is improper. Accordingly, reversal of the rejection of claims 10 and 12 is requested.

D. Claim 11

Dependent claim 11 depends from claim 1 with the addition of low eye irritation potential allowing for direct eye contact. For the same reasons stated in section VIII.B., *supra*, no *prima facie* case of obviousness has been established against this claim.

As the cited reference fails to teach the additional limitations of claim 11 the rejection is improper. Accordingly, reversal of the rejection of claim 11 is requested.

Claims 1-4 and 6-11 were improperly rejected as unpatentable under 35 U.S.C. 103(a) over Heiler et al., (WO 97/43373).

E. The Cited Reference

Heiler et al., teach compositions and methods used as in the eye and/or out of the eye **inhibitors of** proteinaceous deposits on hydrophilic contact lenses. In particular, the compositions contain moderately charged polyquaternium polymers that selectively bind to hydrophilic contact lenses to block the binding of proteinaceous materials.

F. Claims 1-9

Applicants submit that no *prima facie* case of obviousness has been established. Heiler et al. does not teach the present invention or the surprising beneficial effects thereof, such as effective contact lens cleaning of built-up or accumulated deposits of proteins and/or lipids thereon, while remaining gentle enough for direct placement in an eye. The subject compositions comprise a non-amine polyethyleneoxy-containing material having an HLB value of at least 18, a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine, a second non-ionic surface active agent having cleaning activity for contact lens deposits with an HLB value less than that of said non-amine polyethyleneoxy-containing material and a wetting agent, for improved **removal of** contact lens deposits. Heiler et al., does not teach **dual cleaning agents for improved removal of lens deposits**, in addition to comfort agents and wetting agents, as is claimed in the present invention. Contrary to Heiler et al., the subject compositions have

been proven effective in removing lens deposits **without polyquaternium polymers to block protein deposits**. Polyquaternium polymers are taught by Heiler et al., as active ingredients **to prevent** the formation of protein deposits on contact lenses. Accordingly, Heiler et al., teach away from the compositions of the present invention. Heiler et al., teach that moderately charged **polyquaternium polymers are necessary** in a composition to achieve an effective contact lens cleaning solution. However, as disclosed and claimed in the subject application, compositions of the present invention achieve improved cleaning with less eye irritation as compared to commercialized compositions of U.S. Patent Number 5,604,189 without requiring polyquaternium polymers. Accordingly, the subject compositions differ significantly from the teachings of Heiler et al. For these reasons, a *prima facie* case of obviousness has not been established based on Heiler et al. Withdrawal of the rejection of claims 1-4 and 6-11 under 35 U.S.C. 103(a) over Heiler et al. is respectfully requested.

G. Claims 10 and 12

Dependent claims 10 and 12 define compositions of claim 1 with the addition of buffering agents and/or tonicity adjusting agents. For the same reasons stated in section VIII.B., *supra*, no *prima facie* case of obviousness has been established against these claims.

As the cited reference fails to teach the compositions of claims 10 and 12, the rejection is improper. Accordingly, reversal of the rejection of claims 10 and 12 is requested.

H. Claim 11

Dependent claim 11 depends from claim 1 with the addition of low eye irritation potential allowing for direct eye contact. For the same reasons stated in section VIII.B., *supra*, no *prima facie* case of obviousness has been established against this claim.

As the cited reference fails to teach the additional limitations of claim 11 the rejection is improper. Accordingly, reversal of the rejection of claim 11 is requested.

In light of the foregoing arguments, applicants request that the outstanding rejections be reversed and that pending claims 1-12 be allowed.

IX. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

Claim 1 (Previously amended): An aqueous composition for cleaning and wetting a contact lens comprising:

- (a) a non-amine polyethyleneoxy-containing material having an HLB value of at least about 18;
- (b) a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine;
- (c) a second non-ionic surface active agent having cleaning activity for contact lens deposits and that comprises a non-poloxamine surface active agent with an HLB value less than that of said non-amine polyethyleneoxy-containing material; and
- (d) a wetting agent.

Claim 2 (Original): The composition of claim 1 comprising:

- (a) about 0.001 to about 10 weight percent of the non-amine polyethyleneoxy-containing material having an HLB value of at least about 18;

- (b) about 0.001 to about 5 weight percent of the first non-ionic surface-active agent having cleaning activity for contact lens deposits;
- (c) about 0.001 to about 5 weight percent of the second non-ionic surface active agent having cleaning activity for contact lens deposits;
and
- (d) about 0.1 to about 10 weight percent of the wetting agent.

Claim 3 (Original): The composition of claim 2 comprising:

- (a) about 0.001 to about 5 weight percent of the non-amine polyethyleneoxy-containing material having an HLB value of at least about 18;
- (b) about 0.005 to about 2 weight percent of the first non-ionic surface-active agent having cleaning activity for contact lens deposits;
- (c) about 0.001 to about 5 weight percent of the second non-ionic surface active agent having cleaning activity for contact lens deposits; and
- (d) about 0.1 to about 10 weight percent of the wetting agent.

Claim 4 (Original): The composition of claim 1, wherein the non-amine polyethyleneoxy-containing material comprises at least one member selected from the group consisting of poloxamers, ethoxylated glucose derivatives, ethoxylated nonionic ethers of sorbitol, and ethoxylated nonionic ethers of glycerol having an HLB value of at least about 18.

Claim 5 (Original): The composition of claim 4, wherein the non-amine polyethyleneoxy-containing material having an HLB value of at least about 18 comprises an ethoxylated glucose derivative.

Claim 6 (Original): The composition of claim 1, wherein the second non-ionic surface active agent having cleaning activity for contact lens deposits comprises at least one member selected from the group consisting of poloxamers having an HLB value less than 18, ethoxylated alkyl phenols, polysorbates alkyl glucosides and polyglucosides.

Claim 7 (Original): The composition of claim 6, wherein the second non-ionic surface active agent comprises polysorbate 20.

Claim 8 (Original): The composition of claim 1, wherein the wetting agent comprises at least one member selected from the group consisting of cellulosic materials, polyvinylalcohols, polyvinyl pyrrolidones and silicone polymers having a pendant alkyleneoxide side chain.

Claim 9 (Original): The composition of claim 8, wherein the wetting agent comprises a cationic cellulosic polymer.

Claim 10 (Original): The composition of claim 1, further comprising a buffering agent or tonicity adjusting agent.

Claim 11 (Original): The composition of claim 1, wherein eye irritation potential of the composition is sufficiently low such that a contact lens that has been wetted with the composition can be inserted directly in the eye.

Claim 12 (Original): The composition of claim 1, comprising:

- (a) an ethoxylated glucose derivative;
- (b) a poloxamine;
- (c) a polysorbate;

- (d) a cellulosic derivative;
- (e) a borate buffer;
- (f) a polyhexamethylene biguanide or salt thereof; and
- (g) water.

Claims 13 - 20 (Withdrawn)

Should there be any questions regarding this communication, please feel free to contact the undersigned at (636) 226-3340.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rita D. Vacca", with a long horizontal flourish extending to the right.

Rita D. Vacca
Reg. No.: 33,624

Bausch & Lomb, Inc.
One Bausch & Lomb Place
Rochester, New York 14604-2701